

## **REMARKS**

Claims 2-22, 24-40, 43, 44, and 49 have been canceled without prejudice or disclaimer. Claims 1, 23, 45, 50, and 51, as amended, and claims 41, 42, 46-48, and 52-59 are pending in the instant application. No new matter has been added as a result of the above-described amendments. The rejections set forth in the Office Action have been overcome by amendment or are traversed by argument below.

### **1. Rejections of claims 1-59 on obviousness-type double patenting grounds**

The Office Action rejects claims 1-59 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-44 of U.S. Patent No. 6,417,158 (the '158 Patent). The Action states that although the conflicting claims are not identical because the claims in the instant application recite the limitation "wherein said polypeptide is not associated with human urinary proteins," they are not patentably distinct because this limitation is not a true limitation since the proteins in the instant application and the '158 Patent are recombinantly produced and would not be associated with urinary proteins, and the methods of treatment recited in the instant application and the '158 Patent use the same proteins. The Office Action also provisionally rejects claims 1-59 on obviousness-type double patenting grounds as being unpatentable over claims 1-62 of co-pending Application No. 09/898,234 (the '234 application).

Applicants acknowledge the rejections of claims 1-59 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-44 of the '158 Patent, or as being unpatentable over claims 1-62 of the '234 Application, and hereby elect to address these grounds of rejection by submitting a Terminal Disclaimer or by argument upon notification that all other conditions for patentability have been met and the claims are otherwise in condition for allowance.

### **2. Rejections of claims 15-22 and 50-59 under 35 U.S.C. § 112, first paragraph**

The Office Action maintains a rejection of claims 15-22 and 50-59 under 35 U.S.C. § 112, first paragraph, because the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with the claims. The Action states that the specification, while being enabling for making and using a

polypeptide comprising the amino acid sequence set forth in any of SEQ ID NO: 2, SEQ ID NO: 4, SEQ ID NO: 6, SEQ ID NO: 8, SEQ ID NO: 10, SEQ ID NO: 12, SEQ ID NO: 14, SEQ ID NO: 16, SEQ ID NO: 18, or SEQ ID NO: 20, does not reasonably provide enablement for making and using recombinant polypeptide variants of these sequences having at least one conservative amino acid substitution, at least one amino acid substitution at a glycosylation site, at least one amino acid substitution at a proteolytic cleavage site, at least one amino acid substitution at a cysteine residue, at least one amino acid deletion, at least one amino acid insertion, or a combination of these modifications.

The Action also maintains a rejection of the claims under 35 U.S.C. § 112, first paragraph, in so far as the claims encompass an isolated protein other than a recombinant polypeptide comprising the amino acid sequence set forth in any of SEQ ID NO: 2, SEQ ID NO: 4, SEQ ID NO: 6, SEQ ID NO: 8, SEQ ID NO: 10, SEQ ID NO: 12, SEQ ID NO: 14, SEQ ID NO: 16, SEQ ID NO: 18, or SEQ ID NO: 20, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The Action maintains that because the specification merely discloses one polypeptide sequence, the written description does not support the claimed scope and does not fulfill the written description requirements of 35 U.S.C. § 112, first paragraph.

While Applicants respectfully disagree with the Action's assertion that the specification does not reasonably provide enablement for making and using recombinant polypeptide variants of the amino acid sequence set forth in any of SEQ ID NO: 2, SEQ ID NO: 4, SEQ ID NO: 6, SEQ ID NO: 8, SEQ ID NO: 10, SEQ ID NO: 12, SEQ ID NO: 14, SEQ ID NO: 16, SEQ ID NO: 18, or SEQ ID NO: 20, and further, with the Action's assertion that the specification does not convey to one of ordinary skill in the art that the inventors, at the time the application was filed, had possession of the claimed invention, Applicants have amended claims 1, 23, 45, 50, and 51 and have cancelled claims 2-22, 24-40, 43, 44, and 49 in an effort to expedite prosecution of the instant application. Applicants, therefore, respectfully request that the rejections under 35 U.S.C. § 112, first paragraph, be withdrawn.

### **3. Rejection of claim 49 under 35 U.S.C. § 112, second paragraph**

The Office Action maintains a rejection of claim 49 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Specifically, the Action maintains that claim 49 is indefinite for reciting hybridization conditions without reciting the wash conditions.

Applicants respectfully disagree with the assertion that claim 49 is indefinite for reciting hybridization conditions without reciting the wash conditions. However, in an effort to expedite prosecution of the instant application, Applicants have cancelled claim 49, rendering this ground of rejection moot.

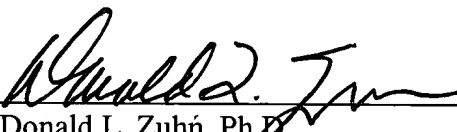
### **CONCLUSIONS**

Applicants respectfully contend that all conditions of patentability are met in the pending claims as amended. Allowance of the claims is thereby respectfully solicited.

If Examiner O'Hara believes it to be helpful, she is invited to contact the undersigned representative by telephone at 312-913-0001.

Respectfully submitted,  
**McDonnell Boehnen Hulbert & Berghoff**

Dated: July 2, 2004

By:   
Donald L. Zuhñ, Ph.D.  
Reg. No. 48,710